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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,823	04/18/2006	Ulrike Stein	BB.243T	2061
23557 7590 07/20/2009 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614			EXAMINER HALVORSON, MARK	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 07/20/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,823	Applicant(s) STEIN ET AL.	
	Examiner Mark Halvorson	Art Unit 1642	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-19, 21-38, 40-42 and 44-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 8, 9, 14-19, 21-38, 40-42 and 44-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13, 47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Claims 1-6, 8-19, 21-38, 40-42 and 44-48 are pending.

Claim 1-6, 8, 9, 14-19, 21-38, 40-42 and 44-46 have been withdrawn.

Claims 10-13, 47 and 48 are under currently under examination.

35 USC § 112 1st paragraph rejection maintained

The rejection of claims 10-13 and new claims 47 and 48 for failing to comply with the enablement requirement is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13, 47 and 48 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the diagnosis of colon cancer, wherein said colon cancer is metastasizing, comprising the step of determining the expression of 7a5/Prognostin in a biological sample from a pathologic tissue and comparison of said expression with the expression of 7a5/Prognostin in a healthy tissue, does not reasonably provide enablement for a method for the diagnosis of breast cancer, wherein said breast cancer is metastasizing, comprising the step of determining

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the expression of 7a5/Prognostin in a biological sample from a pathologic tissue and comparison of said expression with the expression of 7a5/Prognostin in a healthy tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 1 12, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The claims are drawn to a method for the diagnosis of tumour diseases, comprising the step of determining the expression of 7a5/Prognostin in a biological sample from a pathologic tissue and comparing said expression with the expression of 7a5/Prognostin in healthy tissue to determine colon cancer or breast cancer condition, or determining the expression of 7a5/Prognostin in a bodily fluids and comparing said expression with the expression of 7a5/Prognostin in healthy bodily fluid to determine a colon or colorectal cancer condition.

The specification discloses that the expression of 7a5/Prognostin in primary colon tumors correlates with the development of metastasis. (Fig 2). The specification further discloses that the expression of 7a5/Prognostin in primary colon tumours was predictive of metastasis free survival (page 28 4th paragraph to page 29, 1st paragraph). However, in the manuscript figure submitted by Applicants in the May 21, 2008 Reply there does not appear to be any significant difference in the expression of Prognostin in primary colorectal carcinoma cells and metastatic colorectal cancer cells. (Supplemental Figure 1). The specification does not disclose that the expression of 7a5/Prognostin was

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elevated in any other cancer other than colon cancer nor was the expression of 7a5/Prognostin predictive of metastatic spread in any other cancer other than colon cancer. In addition the specification does not disclose the expression of 7a5/Prognostin in bodily fluids.

One cannot extrapolate the teaching of the specification to the scope of the claims because the specification does not provide examples and guidance for diagnosing any other cancer than colon cancer.

Given the disclosure of the specification and teaching in the art, one of skill in the art could not predictably determine that the overexpression of 7a5/Prognostin would be predictive of any tumour disease other than colorectal cancer.

Therefore, in view of the breadth of the claims, lack of guidance in the specification, the absence of working examples, and the state of the art, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

Applicants argue that the claims as amended are supported by the evidence submitted with Applicants response.

Applicants arguments have been considered but are not persuasive. Evidence supporting the enablement of the claims must be submitted in the form of a publication or an affidavit under 37 CFR 1.132. MPEP 2164.05.

Summary

Claims 10-13, 47 and 48 stand rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the

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Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson
Patent Examiner
571-272-6539

/MISOOK YU/
Primary Examiner, Art Unit 1642